GOVERNMENT OF INDIA
HEALTH AND FAMILY WELFARE
LOK SABHA

UNSTARRED QUESTION NO:6340
ANSWERED ON:08.05.2002
PERMISSION FOR NEW DRUGS
B.K. PARTHASARATHI;GANTA SRINIVASA RAO

Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) the number of applications received for the permission of new drugs, bio-equivalence during the year 2001;

(b) the time by which the permission is likely to be given to all applicants;

(c) whether DCGI has discretionary powers to grant permission; and

(d) if so, the number of permission granted under discretionary powers during the period?

Answer

THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE (SHRI A. RAJA)

(a): The following are the number of new drug Applications received during the year 2001:

1. Investigational New Drug (IND) - 2

2. New Drug Applications - 56

3. Subsequent Applications for New Drug approval requiring Bio-equavalence studies - about 400.

(b): Application for permission for New Drugs. Bio-equivalence studies etc. are examined by the New Drug Division in the office of DCG (I).The requirement for granting such approval are specified in Rules 122A, 122B, 122C, 122D and 122E and Schedule Y of Drugs and Cosmetics Rules.The evaluation of new drugs application is a complex process as per Schedule-Y under Drugs and Cosmetics Rules and varies according to the nature of molecule/drug, published data and information furnished by applicants. Therefore, depending upon the nature of the application, it may take on an average more than five years for an applicant to complete all phase of trial required for approval of investigational New Drug (i.e. a drug molecule not tested on human being anywhere in the world) about 1-3 years for the first time approval of the drug already approved elsewhere but requiring confirmatory clinical trial and about 2-3 months for subsequent applications for already approved drugs. This is, however, subject to submission of all required data as per provisions of Schedule Y of Drug and Cosmetics Rules and opinion from experts.Certain critical drugs e.g. anticancer, anti-HIV, immuno-suppressent etc. which are important from the point of view of public health are cleared on a fast track basis.

(c): No, Sir. Permissions are granted after following general norms and taking into account the technical requirements and not on discretion.

(d): Does not arise.